

## **REMARKS**

### **I. Amendments to the specification**

In the specification, the title has been amended so as to introduce “SCN3A”, the elected gene of the present application. Minor clerical errors have been corrected at page 52, line 3 and at page 53, line 3 (~~from~~ instead of form) and page 58, line 15 (~~rat~~ instead of rate). No new matter has been added.

### **II. Status of the claims**

Claims 14-22 were pending at the time of the Action. Claims 14-22 are amended. Claims 23 to 28 are added. Non-limiting support for “a sequence having at least 95% identity...” in claim 14 can be found at page 7, line 3. Non-limiting support for the phrase including the retention of “a biological function of an alpha subunit of a sodium channel” in claims 15, 16, and 28 can be found, for example, at page 17, line 26 to page 18, line 21. *See also* page 17, line 28 to page 18, line 1; page 19, line 20 to page 20, line 19; page 23, lines 13-19. Non-limiting support for new claims 23-28, which directly or indirectly depend from claim 14, can be found in the specification at page 53, line 19 to page 54, line 15 (Example 5), in Figure 7, and in the sequence listing. Thus, no new matter has been entered by way of the instant amendment.

Claims 14-28 are now pending.

### **III. Claim Objections**

Claims 14-16 are objected to because they recite non-elected subject matter. Applicants have elected examination of SEQ ID NO:65 with traverse. Applicants still maintain that the sequences previously recited in claim 15 share the unifying concept of being related to SEQ ID NO:65, because they are comprised therein. Nevertheless, claims 14 and 15 have been amended

to specifically refer to SEQ ID NO:65. Furthermore, claim 16 has been amended to be directed to SEQ ID NO:67, the amino acid sequence encoded by SEQ ID NO:65. Applicants specifically reserve the right to file one or more divisional applications directed to non-elected subject matter.

In view of the fact that claims 14-16 are directed to the elected sequence identifiers, Applicants respectfully submit that the objection to claims 14-16 has been rendered moot.

#### **IV. Claims Rejections Under 35 U.S.C. § 101**

Claims 20-22 are rejected as being directed to non-statutory subject matter. Claims 20-22 are now directed to “An isolated cell”, as suggested by the Examiner. Therefore, pending claims 20-22 are directed to statutory subject matter and the rejection under U.S.C. § 101 is moot.

#### **V. Rejections Under 35 U.S.C. § 112**

##### **A. Claims 14-22 satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph**

Claims 14-22 are rejected under 35 U.S.C. § 112, first paragraph as not complying with the enablement requirement. Specifically, the claims are rejected based on alleged insufficient enablement for all fragments, functional derivatives, or allelic variants.

To satisfy the enablement requirement the claimed invention must be described in a way to enable any person skilled in the art to make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Applicants disagree with the rejection. However, in an effort to further the prosecution and secure prompt allowance, Applicants note that claim 14 is directed to a nucleic acid sequence selected from the group consisting of (a) the nucleic acid of SEQ ID NO: 65; which encodes an alpha subunit of a sodium channel, (b) a complement of (a); and (c) a nucleic acid

sequence having at least 95% identity overall to the nucleic acid sequence in (a) or (b). The objected terminologies having been deleted, the rejection of claim 14 has been rendered moot.

Claims 15 and 16 are directed to a fragment, functional derivative or allelic variant that “retains a biological function of an alpha subunit of a sodium channel”, as requested by the Examiner. In view of the recitation that the nucleic acid of claim 16 encodes “the complete amino acid sequence of SEQ ID NO:65”, the term “fragment” has been removed therefrom. In view of these amendments, the state of the art, and the guidance from the specification on the types of assays which can be used to identify fragments, derivatives or variants which retain a biological activity of an alpha subunit of a sodium channel (as described for example, from page 37, lines 12 to page 43, line 13; from page 44, line 27 to page 50, line 4; and in example 7), it is respectfully submitted that claims 14-22 are enabled and satisfy the written description requirement (e.g., they comprise a “definition, such as by...physical properties”). Applicants wish to state that the level of skill in the art has significantly increased since the publication of Rudinger 30 years ago.

**B. Claims 14-22 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph**

Claims 14-22 have been rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirements. Specifically, the Action alleges that the description of the application would not “reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention “, “nucleic acids”, “fragments”, “functional derivatives”, or “allelic variants”.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the

inventor had possession of the claimed invention. *See, e.g., Moba, B. V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003).

Applicants disagree with the rejection. However, in an effort to further the prosecution and secure prompt allowance, Applicants note: (1) claim 14 is directed to nucleic acids having at least 95% identity to SEQ ID NO:65; and (2) claim 15 recites that a fragment, functional derivative, or allelic variant retains a biological function of an alpha subunit of a sodium channel. In light of the argument presented above, it is respectfully requested that the Examiner withdraws his rejection of claims 14-22 under 35 U.S.C. § 112, first paragraph, for lack of written description.

#### **VI. Rejections Under 35 U.S.C. § 102(b)**

Claims 14-22 have been rejected as being allegedly anticipated by Clare *et al.* (Conference on Molecular and Functional Diversity of Ion Channels and Receptors, New York, NY May 14-17, 1998, published as Annals of the New York Academy of Sciences 1999, 868:80-83). Applicants respectfully traverse the rejection.

Applicants do not agree with the Examiner's allegation that Clare *et al.*, is a "Meeting Paper... held 14-17 May 1998". In any event, Clare *et al.*, allegedly discloses the cloning of a type III alpha subunit from human brain, a detection of a mRNA of approximately 9.5kb in brain and heart tissues, as well as of a 7.5kb fragment in skeletal muscle. Applicants agree with the Examiner that Clare *et al.*, fails to disclose the sequence set forth in SEQ ID NO:65. The Examiner alleges SEQ ID NO:65 is an inherent property of the product.

Applicants submit that for a reference to anticipate based on inherency, the inherency must be "certain". This has been established long ago by legal precedent:

When an anticipation is based upon inherency, however, the inherency **must be certain**, i.e., the inherency may not be established by probabilities or possibilities" [emphasis added]

*In re Oelrich*, 666 F. 2d 578, 581 (CCPA 1981); *see also* and *Ex parte Cyba*, 155 USPQ 756, 757 (Bd. App. 1966) ("In order that a rejection based upon inherency may be sustained such inherency **must be certain**.") (emphasis added).

The mere fact that the nucleic acid of the prior art has a similar size as the nucleic acid of the present invention (9.5kb as compared to 9.1kb, respectively), is clearly insufficient to establish that these nucleic acids are identical, and therefore that the sequence of SEQ ID NO:65 is an inherent property of the nucleic acid disclosed in the prior art. In fact, the Examiner seems to agree by stating: "The Prior Art product, reported to be "˜9.5 Kb" appears to be identical to the invention now claimed" (emphasis added). It is known that sodium channels show high homology in several regions and it is therefore impossible to establish that the probe used by Clare *et al.*, detects the nucleic acid of the present invention, and not the nucleic acid of the alpha subunit of any other sodium channel (especially considering the fact that the sequence of the probe as well as the hybridization conditions used are not disclosed). Indeed, the detection of a 7.5kb band in skeletal muscle strongly suggest that the probe used by Clare *et al.*, is not specific to SCN3A, as SCN3A is not expressed in skeletal muscle (Thimmapaya R. et al. (2005), Eur. J. Neurosci., 22(1):1-9). It appears that the probe used by Clare *et al.*, detects the nucleic acid encoding another sodium channel known as SCN4A, which is between 7.5kb and 8.0kb in size and is highly expressed in skeletal muscle (Wang et al. (1992), Biochem. Biophys. Res. Commun., 182 (2), 794-801). Moreover, it is also well known that ion channels, such as voltage-gated sodium channels, have similar sizes. It is therefore inappropriate to solely rely on the size of the nucleic acid as evidence of identity to the nucleic acid of the present invention. Finally, Figure 1C of Clare *et al.* demonstrates that the  $V_{1/2}$  (inactivation voltage) of the sodium channel

identified and cloned is 58mV, whereas the reported  $V_{1/2}$  for SCN3A is 69mV (Chen YH et al. (2000), Eur. J. Neurosci., 12 : 4281-4289), again suggesting that the nucleic acid disclosed by Clare is not SCN3A.

In view of the foregoing, and in particular, the above described evidence showing that inherency is clearly not “certain” based on Clare *et al.*, Applicants respectfully request that the Examiner withdraws the rejection of claims 14-22 under 35 U.S.C. § 102 (b)

Claims 14-19 have been rejected as being allegedly anticipated by Lu (1998, Journal of Molecular Neuroscience 10(1): 67-70), as evidenced by sequence alignment for NCBI Accession Numbers AF035685 and AF035686 allegedly.

Applicants disagree. However, in an effort to further prosecution and secure prompt allowance, Applicants note that AF035685 and AF035686 are 98.3% and 99.1% identical to SEQ ID NO:65, respectively, “over the region from bases 2-4147, using Applicant’s numbering system”. In view of (1) the length of SEQ ID NO:65, which is 9,112 nt; (2) the amendment to claim 14 which introduces “having at least 95% identity overall”; and (3) the deletion of the term “fragment”, Applicants respectfully submit that Lu *et al.*, fails to disclose a nucleic acid having 95% identity to SEQ ID NO:65 (or to a complement thereof) and respectfully submits that claim 14 is novel over Lu *et al.*.

Furthermore, while Lu *et al.* discloses a fragment of SCN3A transcript, it fails to disclose or suggest that the nucleic acid fragment has a biological function of an alpha subunit channel of a sodium channel. Therefore, claims 15 and 16, which recite such a limitation, are not anticipated by Lu *et al.* Consequently, claims 17-19, which directly depend from claims 14 to 16, are also novel over this reference.

In view of the foregoing, Applicants respectfully request that the Examiner withdraws the rejection of claims 14-19 under 35 U.S.C. § 102 (b).

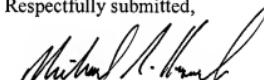
## VII. Conclusion

The present document is a full and complete response to the August 21, 2006 Office Action. This case is in a condition for allowance, and such favorable action is requested.

A petition for a two-month extension of time is being electronically filed along with this paper. Should any fees be required under 37 C.F.R. §§ 1.16 to 1.21 for any reason relating to the enclosed materials, the Commissioner is authorized to deduct said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/GOUD:023USD3.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3020 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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